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Title: A proof of concept study by thrombomodulin for acute exacerbations of idiopathic pulmonary fibrosis

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Body: The mortality of acute exacerbation of idiopathic pulmonary fibrosis (AE-IPF) is high. Anticoagulation therapy (recombinant human soluble thrombomodulin (rhTM)) is recognized as treating disseminated intravascular coagulation. The aim was to evaluate whether the coagulation factors were detected in AE-IPF, and whether the rhTM treatment for AE-IPF-patients has beneficial effects. We retrospectively reviewed the data of AE-IPF, IPF with pneumonia and slowly progressive IPF-patients. Next, AE-IPF-patients were prospectively treated with rhTM under mechanical ventilation. The primary outcome was the improvement of oxygenation and intravascular coagulation disturbance in the acute phase. The secondary endpoints were the improvement of high-mobility group box-1 (HMGB-1). Eleven AE-IPF, 21 IPF with pneumonia and 16 slowly progressive IPF-patients were enrolled, and the plasma coagulatory levels of the AE-IPF-patients were found to be significantly higher than in the other patients. In a prospective study of the rhTM administration for 20 AE-IPF-patients, the 28-day mortality and in-hospital mortality were 35% and 45%, respectively. The SpO₂/F_IO₂ rapidly increased on day 1 and continued to improve until day 7 in the survivors. The thrombin-antithrombin complex levels in the survivors on day 7 were significantly different from those observed in the nonsurvivors. The levels of HMGB-1 in the nonsurvivors were significantly higher on day 7 compared to those observed in the survivors. Adding the administration of rhTM may improve pulmonary dysfunction in AE-IPF-patients, as demonstrated by significant improvements in oxygenation and microvascular coagulation.